

REMARKS

Applicants appreciate the Examiner's thorough examination of the subject application and request reconsideration of the subject application based on the foregoing amendments and the following remarks.

Claims 1-22 and 42-66 are pending in the subject application.

Claims 42-54, 56-62 and 66 are withdrawn from consideration as the result of an Examiner's earlier restriction requirement. Claims 56-62 are canceled. In view of the Examiner's earlier restriction requirement, Applicants reserve the right to present the other of the above-identified withdrawn claims in a divisional application.

Claims 1-13, 156-21, 55 and 63-65 stand rejected under 35 U.S.C. §102 and/ or 35 U.S.C. §103. Claims 14 and 22 were objected to as depending from a rejected base claim, however, the Examiner indicated that the claims would be allowable if appropriately re-written in independent form.

Claims 1 and 55 were amended for clarity and to more distinctly claim Applicant's invention. The amendments to the claims are supported by the originally filed disclosure.

35 U.S.C. §102 REJECTIONS

The Examiner rejected claim 1 under 35 U.S.C. §102(b) as being anticipated by Banko [USP 3,618,594; Banko '594]. Applicants respectfully traverse as discussed below. Because claims were amended in the instant amendment, the following discussion refers to the language of the amended claims. However, only those amended features specifically relied upon to distinguish

the claimed invention from the cited prior art shall be considered as being made to overcome the cited reference.

Applicants claim, claim 1, a method for providing access within an eye during an ocular surgical procedure. Such a method includes providing an entry alignment device that is configured so as to provide an entry aperture in each of the conjunctiva and sclera of the eye and maintaining the entry aperture in each of the conjunctiva and sclera aligned during the surgical procedure and inserting the entry alignment device into the eye so as to form the entry apertures, where said inserting is accomplished without pulling back of the conjunctiva.

In the foregoing amendment, claim 1 was amended to provide that said inserting is accomplished without *pulling back the conjunctiva* and the language “an incision in the conjunctiva or the sclera” is removed in view of the added language. It should be noted that the withdrawal of the prior language shall not be considered an acquiescence of Applicants to the rejection and the assertion that claim 1 with such language is anticipated by Banko.

As indicated by Applicants during the personal interview, one skilled in the art would have recognized that Banko '594 had not fully described the surgical process being implemented and that certain language is missing from Banko '594. However, certain of the disclosure and discussion in Banko '594 *does reveal* to those skilled in the art the methodology and device being disclosed in Banko '594, including the missing language and techniques.

As described in the subject application (see page 2, lines 4-1) current vitreoretinal techniques in which surgical instruments are inserted into the eye require the dissection of the conjunctiva 4 and the creation of pars plana scleral incisions through the sclera 6. As is also clear

from the discussion in the subject application, the conjunctiva is dissected and pulled back so as to expose the area(s) of the sclera where the pars plana scleral incisions are to be made in the sclera or the wall of the eye. Such dissection typically involves cutting a portion of the conjunctiva and then pulling back on the edges of the cut portion to expose the sclera and which also may include clipping or otherwise securing the pulled back edges of the cut portion so as to maintain the field of view for the sclera clear of the conjunctiva. Some terms used to refer to the cutting of the conjunctiva are "conjunctival incision" or "dividing the conjunctiva." When the conjunctiva is "incised" or "divided," blunt conjunctival dissection is performed near the incision to clear an area for a sclerotomy.

Applicants respectfully submit that the technique described in Banko '594 and the device, in particular the cutting blade or instrument make clear that a necessary element of the methodology described in Banko '594, and thus a design feature necessarily embodied by the device disclosed in Banko '594 is that the conjunctiva is first pulled back to expose the sclera before the device is inserted through the wall of the eye.

In order to understand the disclosure in Banko '594, it is first necessary to understand the relationship between the conjunctiva and the wall of the eye. As provided in Banko '594, the wall of the eye is intended to include any portion of the eye which when pierced will connect the interior of the eye to the exterior and will generally include all, or portions, of the retina, choroid, sclera and cilia body. See Banko '594, col. 4, lines 7-11. As described in Gray's Anatomy(15th Edition), the conjunctiva is the mucous membrane of the eye that lines the inner surface of the eyelids and is reflected over the fore part of the sclerotic and cornea. Also, and as is well known to those skilled

in the art, the conjunctiva is a layer of tissue that is separate and apart from the wall of the eye as the conjunctiva is physically grasped, pulled and cut without involving the wall or sclera of the eye when performing such dissections. Thus, the conjunctiva is a separate layer that is loosely connected to the globe but does not form a portion of the wall of the globe comprising the eye. Also, piercing of the conjunctiva merely establishes an opening between the exterior surface of the conjunctiva and the exterior surface of the wall 25 of the eye; not the exterior surface of the wall 25 of the eye and the interior of the eye in which is found the vitreous material.

As to the supporting means 50, Banko '594 describes that once the supporting means is inserted into and through the wall of the eye, two mattress sutures 52 may be conveniently tightened so as to prevent any of the vitreous material within the eye from flowing out. It also is provided that such tightening of the mattress sutures establishes sealing engagement between the supporting means 50 and the wall 25 of the eye. See Banko '594, col. 6, lines 16-20, col. 7, lines 9-13. Banko '594 further describes that when removing the supporting means, an additional pair of mattress sutures are to be gradually tightened as the supporting means is gradually removed from the wall to close-up the opening 27 in the wall 25 of the eye.

As indicated above, and is known to those skilled in the art, the conjunctiva is not part of the wall of the posterior segment of the eye including the retina, choroid, sclera and cilia body. As is also known to those skilled in the art, a sclerotomy is an incision that is made in the sclera/ wall of the posterior segment of the eye, more preferably in the pars plana. Thus, and is known to those skilled in the art, the sclera must be exposed in order to allow the placement of the mattress sutures referred to in the above identified portions of Banko '594. Thus, and although not explicitly stated

in Banko `594, it necessarily follows from the foregoing passages in Banko `594 that the conjunctiva is being dissected and pulled back to expose these portions of the sclera prior to insertion of the support means as well as for suturing closed the opening formed in the sclera/ wall of the eye.

Applicants would note that Banko `594 in col. 1, lines 7-12 provides that reference should be made to a copending application now USP 3,528,425 [Banko `425] and that the disclosure in Banko `425 discloses the method and apparatus for forming an opening or incision in the eye and the performing of surgical procedures. The disclosure in Banko `425 also includes reference to the tightening of the mattress sutures 52 to prevent vitreous material from leaking out and the use of these sutures or other mattress sutures to seal the opening after the support means is received.

It also necessarily follows from the foregoing discussion from Banko `594 that the sclerotomy is not self-sealing as sutures are being used to seal the opening or sclerotomy. This is not surprising as the blade or piercing end shown in Figures 6-7 and described in Banko `594, as well as that more specific information disclosed and shown in Banko `425, is arranged so as to form an opening that would not be self-sealing.

In sum, Banko `594 does not disclose, suggest nor teach either expressly or inherently, a methodology where an entry alignment device is inserted through the conjunctiva and wall of an eye to form entry apertures in each of the conjunctiva and the wall/ sclera, where the insertion is accomplished without the pulling back of the conjunctiva.

As provided in MPEP-2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.

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Verdegel Bros. v. Union Oil Co. of California, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Or stated another way, "The identical invention must be shown in as complete detail as is contained in the ... claims. *Richardson v Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ 2d. 1913, 1920 (Fed. Cir. 1989). Although identify of terminology is not required, the elements must be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990). It is clear from the foregoing remarks that the above identified claim is not anticipated by Banko '594.

It is respectfully submitted that for the foregoing reasons, claim 1 is patentable over the cited reference and satisfy the requirements of 35 U.S.C. §102(b). As such, this claim, including the claims dependent therefrom, is allowable.

35 U.S.C. §103 REJECTIONS

Claims 1-13, 15-21, 55 and 63-65 stand rejected under 35 U.S.C. § 103 as being unpatentable over the cited prior art for the reasons provided on pages 2-4 of the above-referenced Office Action. Because claims were amended in the foregoing amendment, the following discussion refers to the language of the amended claim(s). However, only those amended features specifically relied on in the following discussion shall be considered as being made to overcome the prior art reference. The following addresses the specific rejections provided in the above-referenced Office Action.

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CLAIMS 1-12, 55 & 63

Claims 1-12, 55 and 63 stand rejected as being unpatentable over Peyman [USP 5,487,725] in view of Banko [USP 3,618,594; Banko `594] for the reasons provided on page 2-3 of the above referenced Office Action. Applicants respectfully traverse.

The above-referenced Office Action admits that Peyman discloses a surgical procedure that does not utilize entry alignment devices and that Banko `594 teaches that entry alignment devices are used in surgical procedures to provide stability and a supporting point for the surgeon's hand. Thus, it is concluded that it would have been obvious to one skilled in the art to use the device disclosed in Banko `594 in the method disclosed in Peyman. Applicants respectfully traverse and also respectfully disagree with the characterization of what is being allegedly disclosed in Peyman and Banko `594 as well as that such teaching would yield the methodology and devices of the present invention.

As to Peyman, and as admitted in the above-referenced Office Action, this reference does NOT disclose nor teach a surgical procedure that uses an entry alignment device. As provided in the discussion above regarding Banko `594, the conjunctiva is a layer of tissue that is separate and apart from the wall of the eye and the conjunctiva is physically grasped, pulled and cut without involving the wall or sclera of the eye when performing such dissections. Thus, the conjunctiva is a separate layer that is loosely connected to the globe but does not form a portion of the wall of the globe comprising the eye. Also, piercing of the conjunctiva merely establishes an opening between the exterior surface of the conjunctiva and the exterior surface of the wall of the eye; not the exterior surface of the wall of the eye and the interior of the eye in which is found the vitreous

material. It thus, necessarily follows that Peyman also cannot include any suggestion or teaching to combine the use of a transconjunctival entry alignment device with the surgical procedure disclosed and taught in Peyman.

Further, and as was indicated in Applicants' remarks included with Applicants' Response dated December 17, 2002, Peyman discloses the known technique of making a *sclerotomy incision* (i.e., an incision in the sclera) and inserting a probe through the sclerotomy incision into the vitreous cavity. See Abstract and col. 4, lines 47-49 thereof. As is known to those skilled in the art, to make this incision in the sclera the conjunctiva is first dissected or pulled back to expose the sclera. It also might be possible to make a large incision in the conjunctiva so as to expose the sclera sufficiently to make the required sclerotomy incision.

As noted above, the Office Action admits that Peyman nowhere makes reference to, nor suggests, an entry alignment device. As also indicated above, the surgical procedure taught and disclosed in Peyman uses the well known technique of making a sclerotomy incision so the probe can be inserted into the vitreous cavity. Thus, Peyman does not and cannot disclose, suggest or teach, explicitly or inherently, the transconjunctival methodology claimed by Applicants.

As indicated in the discussion above, regarding the §102 rejection of claim 1, Banko '594 does not disclose, suggest nor teach either expressly or inherently, a methodology where an entry alignment device is inserted through the conjunctiva and wall of an eye to form entry apertures in each of the conjunctiva and the wall/ sclera, where the insertion is accomplished without the pulling back of the conjunctiva. In addition, there is no teaching, suggestion or motivation offered in Bano

`594 to modify the method disclosed in Peyman so as to yield or teach, explicitly or inherently, the transconjunctival methodology being claimed by Applicants.

In sum, each of the cited references describes a methodology in which an incision is made in the eye prior to insertion of the surgical instruments (Peyman) or the support means (Banko `594). As is known to those skilled in the art, and as more particularly discussed in connection with the §102 rejection herein, making an incision in the sclera of the posterior segment necessarily involves the dissection or pulling back of the conjunctiva prior to expose the sclera. Thus, none of the cited references can explicitly or inherently disclose the method of claim 1 in which both the conjunctiva and the sclera can be traversed and penetrated by the entry alignment device. In addition, Peyman and Banko `594 alone or in combination do not teach nor suggest the method of the present invention. Moreover, there is no teaching, suggestion nor motivation offered in either of the cited references to modify the methodology disclosed in the primary reference, Peyman, so as to yield either of the methodologies claimed by Applicants.

It is respectfully submitted that the foregoing arguments, also apply to distinguish claim 55 and the claims that depend respectively from either of claims 1 or 55 from the cited combination of references.

It is respectfully submitted that claims 1-12, 55 and 63 are patentable over the cited reference(s) for the foregoing reasons.

CLAIMS 13, 15-21, 64 & 65

Claims 13, 15-21, 64 and 65 stand rejected as being unpatentable over Peyman in view of Banko '594 and further in view of Saperstein et al. (USP 5,919,158; "Saperstein") for the reasons provided on pages 3-4 of the above referenced Office Action. Applicants respectfully traverse.

Claims 13, 15-24, 64 and 65 depend respectively from one of claims 1 or 55. As indicated above, Peyman and Banko '594 alone or in combination do not disclose, teach nor suggest the methods as set forth in either of claims 1 or 55. Moreover, there is no teaching, suggestion nor motivation offered in either of the cited references to modify the methodology disclosed in the primary reference, Peyman, so as to yield either of the methodologies claimed by Applicants. As such, each of claims 13, 15-21, 64 and 65 are considered to be in allowable form at least because of their dependency from an independent claim that is considered to be allowable. As to the tertiary reference, Saperstein, Applicants make the following observations.

Saperstein is used in the grounds for the rejection for the limited purpose of teaching the use of a light source to illuminate an area. Saperstein, however, also describes the known technique of inserting surgical instruments/ cannulas/ light probe through a sclerotomy (*i.e.*, sclerotomy incision) in the eye. Thus, Saperstein does not disclose, teach or suggest the transconjunctival methodology claimed by Applicants. Moreover, there can be no teaching, suggestion or motivation offered in the tertiary cited reference to modify the methodology disclosed in the primary reference, Peyman, so as to yield either of the methodologies claimed by Applicants.

In sum, each of the cited references describes a methodology in which an incision is made in the eye prior to insertion of the surgical instruments (Peyman and Saperstein) or support menas

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of Banko '594. As is known to those skilled in the art, making an incision in the sclera of the posterior segment necessarily involves the dissection or pulling back of the conjunctiva prior to expose the sclera. Thus, the cited references do not explicitly nor inherently disclose the methods as set forth in claims 1 or 55 in which both the conjunctiva and the sclera of an eye are traversed and penetrated by the entry alignment device. In addition, Peyman and Banko '594 alone or in combination do not teach nor suggest the methods of the present invention. Moreover, there is no teaching, suggestion nor motivation offered in any of the cited references to modify the methodology disclosed in the primary reference, Peyman, so as to yield either of the methodologies of claims 1 and 55 claimed by Applicants.

It is respectfully submitted that claims 13, 15-24, 64 and 65 are patentable over the cited reference(s) for the foregoing reasons.

The following additional remarks shall apply to each of the above.

As provided in the foregoing remarks, the cited references do not teach or suggest the features of the provided entry alignment device claimed by Applicant. Further, the cited references do not teach or suggest the combination of steps of the method claimed by Applicants. In addition, there is no suggestion anywhere in these references that such a combination would be reasonably successful.

The Federal Circuit has indicated in connection with 35 U.S.C. §102 that in deciding the issue of anticipation, the trier of fact must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify *corresponding elements* disclosed in the allegedly anticipating reference (emphasis added, citations in support omitted).

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Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Company et al., 730 F. 2d 1452, 221 USPQ 481,485 (Fed. Cir. 1984). Notwithstanding that the instant rejection is under 35 U.S.C. §103, in the present case the Examiner has not shown that the devices and method steps in any of the cited references corresponds, as that term is used above by the Federal Circuit, in any fashion to the provided entry alignment devices and methodology in their entire claimed form as set forth in any of claims 1, 13 and 55 of the present invention.

As provided in MPEP 2143.01, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F. 2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F. 2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). As provided above, the references cited, alone or in combination, include no such teaching, suggestion or motivation.

It is respectfully submitted that for the foregoing reasons, claims 1-13, 15-21, 55 and 63-65 are patentable over the cited reference(s) and satisfy the requirements of 35 U.S.C. §103. As such, these claims are allowable.

OTHER MATTERS

Applicants have concurrently filed a Supplemental Information Disclosure Statement to identify an article recently brought to attention of the licensee. Accordingly, Applicants respectfully request that the Examiner reflect their consideration of this IDS in the next official communication

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from the USPTO. Applicants also respectfully request the Examiner to call the undersigned collect and the below number in the event that this IDS has not been received by the Examiner and thus needs to be again submitted by Applicants for the Examiner's consideration.

It is respectfully submitted that the subject application is in a condition for allowance. Early and favorable action is requested.

Applicants believe that additional fees are not required for consideration of the within Response. However, if for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, the Commissioner is hereby authorized and requested to charge Deposit Account No. 04-1105.

Respectfully submitted,
Edwards & Angell, LLP

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